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10/599,401

02/27/2007

Seth Hallstrom

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06/18/2009

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EXAMINER

LIU, SAMUEL W

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

06/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/599,401 | <b>Applicant(s)</b><br>HALLSTROM ET AL. |  |
|                              | <b>Examiner</b><br>SAMUEL W. LIU     | <b>Art Unit</b><br>1656                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

Claims 1-18 are pending

The preliminary amendment filed 2/27/07 which amends claims 1-7, and adds claims 8-18 has been entered. The following Office action is applied to claims 1-18.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

NOTE: instant claims 1-18 are drawn to "use claims" (for the use of SH-group containing protein or compound) lacking the steps (see MPEP 7.34.06); the claims have been interrelated as directed to a method of manufacturing a pharmaceutical preparation comprising the protein or the compound thereof, **or** a method of treating a disease/disorder (see claim 1) by administering (see claim 4 limitation) to a subject in need said protein or compound, or said preparation. The following restriction requirement is based on this claim interpretation.

Restriction is required under 35 U.S.C. 121 and 372.

Group I, claims 1-18, drawn to a method of manufacturing a pharmaceutical preparation comprising the protein or the compound which comprising nitrosated SH-group (see p.3, 2<sup>nd</sup> paragraph, the specification) of a protein or a compound.

Group II, claims 1-18, drawn to a method of treating a disease/disorder by administering to a subject in need the protein or compound, or said preparation.

The method (or use of the protein or the compound for the treatment) of Group II, claims 1-3, 5, 7, 8, 11, 14, 15 and 17 are obvious over Schlag et al. (US Pat. No. 6358918 B1). Prior to the effective filing date of the instant application, at patent claims 25 and 27-30, Schlag et al. disclose a method of treating a patient suffering from shock, particular traumatic shock (col. 7, lines 2-3) comprising administering to the patient the pharmaceutical composition comprising the thiol-containing protein such as albumin (claim 26) wherein the albumin is nitrosated (claims 25 and 30) wherein at least 70-90% of thiol groups of the protein are nitrosated (claim 29). Therefore, the claimed protein or the pharmaceutical preparation comprising the protein thereof does not constitute a special technical feature linking all claims, as defined by PCT Rule 13.2

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and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

### ***Additional Election Under 35 USC 121***

Applicants are further required under 35 US 121 (1) to elect a single disease/disorder state or/and a single disclosed molecule to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

(1) If Group I **or** II is elected, applicants are required to elect one disease/disorder state from claim 1 because the patient populations and pathological mechanisms are distinct/different among the diseases/disorders or conditions recited in claim 1; e.g., the population and pathology of erectile dysfunction *versus* those of respiratory tract disease or those of ischemia; the “erectile dysfunction” is a disorder of inability to achieve and/or maintain an erection sufficient for satisfactory sexual intercourse in men (see Boston Medical Group (2009, updated) What is Erectile Dysfunction?, [www.bostonmedicalgroup.com/erectile-dysfunction?kmas=1&kmca=bmg\\_erectiledysfunction&kmag=condition&kmkw=erectile+dysfunction&utm\\_source=google&utm\\_medium=ppc&utm\\_term=erectile\\_dysfunction&utm\\_campaign=BMG\\_Erectile%20Dysfunction&gclid=CJG6sJixhZsCFZpM5QodM0k8oQ](http://www.bostonmedicalgroup.com/erectile-dysfunction?kmas=1&kmca=bmg_erectiledysfunction&kmag=condition&kmkw=erectile+dysfunction&utm_source=google&utm_medium=ppc&utm_term=erectile_dysfunction&utm_campaign=BMG_Erectile%20Dysfunction&gclid=CJG6sJixhZsCFZpM5QodM0k8oQ), pages 1-3).

(2) If Group I **or** II is elected, applicants are required to elect one protein from claims 3 and 8, because the structure (amino acid sequence) and biological function of proteins such as albumin, fibrinogen and hemoglobin are distinct from one another.

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 US 121 since the above-mentioned disorder/disorder states (claim 18) do not substantially overlap in patient populations and are distinct in pathology, treatment schedules and outcomes, e.g., erectile dysfunction *versus* those of respiratory tract disease, and since, as discussed above, the structures and biological functions of the proteins (e.g. albumin *versus* hemoglobin) are distinct from one another, and thus, they are directed to independent inventions or/and patentably distinct from one another.

### ***Species election***

This application contains claims directed to the following patentably distinct species:

Claims 4, 6, 9 and 13 of Group I or Group II are directed to the different species, i.e., different compounds. The species are distinct because the chemical structures or/and activities of

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the compounds recited in the claims, e.g., glutathione, captopril (an angiotensin-converting enzyme inhibitor) and dihydrolipoic acid are distinct/different from one another.

Because these species are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for the species election and for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). Currently, claims 1, 2 and 4 are generic.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Andrew Wang can be reached on (571) 272-0811. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

/Samuel W Liu/

Examiner, Art Unit 1656

June 12, 2009

/ANAND U DESAI/

Primary Examiner, Art Unit 1656